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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for topical use of ivermectin on cattle to control infections and prevent reinfection with certain species of external and internal parasites.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *jmessenh@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 140–841 for IVOMEC (ivermectin) Pour-On for Cattle. The application provides for topical use of 0.5 percent ivermectin solution on cattle to control infections and prevent reinfection with *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment, *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment, *C. surnabada* for 14 days after treatment, and *Damalinia bovis* for 56 days after treatment. The NADA is approved as of November 24,

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2003, and § 524.1193 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulation is revised to remove two species of parasites, *Oesophagostomum venulosum* and *Chorioptes bovis*, which were codified in error during the original approval NADA 140–841 (55 FR 50551, December 7, 1990). Also at this time, the indication for *Cooperia* spp. is speciated as *Cooperia oncophora*, *C. punctata*, and *C. surnabada* to conform with current labeling practices. A veal calf warning statement is being added because residue depletion data for this class of cattle has not been submitted to the application.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning November 24, 2003. Exclusivity applies only to the extension of the persistent effectiveness claims for *O. radiatum* from 14 days after treatment to 28 days after treatment and for *C. punctata* and *T. axei* from 14 days after treatment to 21 days after treatment, and to the new persistent effectiveness claims for *D. viviparus*, *C. surnabada*, and *D. bovis* for which new data were required.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant

impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 524.1193 is amended by revising paragraphs (b), (e)(1), and (e)(2), and by adding two sentences to paragraph (e)(3) to read as follows:

§ 524.1193 Ivermectin topical solution.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 050604 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(iii), and (e)(3) of this section.

(2) Nos. 051259, 051311, 058829, 059130, and 066916 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

* * * * *

(e) *Conditions of use in cattle*—(1) *Amount.* One mL per 22 pounds (0.5 milligram per kilogram) of body weight applied topically to the back of the animal.

(2) *Indications for use*—(i) It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. surnabada, Oesophagostomum radiatum*; (adults) *Strongyloides papillosus, Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis, H. lineatum*; mites *Sarcoptes scabei* var. *bovis*; lice *Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenoptes capillatus*; and horn flies *Haematobia irritans.*

(ii) It controls infections and prevents reinfection with *O. ostertagi, O. radiatum, H. placei, T. axei, C. punctata,* and *C. oncophora* for 14 days after treatment.

(iii) It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *H. placei, C. oncophora,* and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

(3) * * * A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal.

Dated: December 24, 2003

December 24, 2003.

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